#### 111TH CONGRESS 1ST SESSION

# H. R. 4216

To amend the Public Health Service Act and titles XVIII and XIX of the Social Security Act to establish guidelines to enhance the meaningful use and interoperability of electronic medical records with personal health records, including for purposes of Medicare and Medicaid payment incentives.

#### IN THE HOUSE OF REPRESENTATIVES

**DECEMBER 7, 2009** 

Mr. Kennedy (for himself and Mr. Reichert) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

## A BILL

To amend the Public Health Service Act and titles XVIII and XIX of the Social Security Act to establish guidelines to enhance the meaningful use and interoperability of electronic medical records with personal health records, including for purposes of Medicare and Medicaid payment incentives.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,

### 1 SECTION 1. SHORT TITLE.

| 2  | This Act may be cited as the "Personal Health         |
|----|---|
| 3  | Record Act of 2009".                                  |
| 4  | SEC. 2. ENHANCING MEANINGFUL USE OF ELECTRONIC        |
| 5  | HEALTH RECORDS THROUGH INTEROPER-                     |
| 6  | ABILITY.  |
| 7  | (a) Definitions.—                                     |
| 8  | (1) In General.—Section 3000 of the Public            |
| 9  | Health Service Act (42 U.S.C. 300jj) is amended by    |
| 10 | adding at the end the following:                      |
| 11 | "(15) ELECTRONIC EXCHANGE.—The term                   |
| 12 | 'electronic exchange' shall include the automated     |
| 13 | transfer of individual health information between     |
| 14 | electronic medical records and personal health        |
| 15 | records, and between electronic medical records, per- |
| 16 | sonal health records, and other electronic systems.   |
| 17 | "(16) Personal Health Record.—The term                |
| 18 | 'personal health record' means an electronic record   |
| 19 | of PHR identifiable health information (as defined    |
| 20 | in section $13407(f)(2)$ of the HITECH Act) of an     |
| 21 | individual that—                                      |
| 22 | "(A) complies with appropriate data con-              |
| 23 | tent standards;                                       |
| 24 | "(B) enables the individual, an authorized            |
| 25 | representative, vendor of personal health             |
| 26 | records (as defined in section 318.2(j) of title      |

16, Code of Federal Regulations, as in effect as of November 1, 2009), any covered entity (as defined for purposes of HIPAA privacy and se-curity law, as defined in section 3009(a)(2), or an entity to the extent that it engages in activi-ties as a business associate (as defined for such purposes) of such a covered entity, to retrieve data from or input data into the electronic record; and

- "(C) is portable and capable of electronic communication between such individual and the relevant covered entity, business associate described in subparagraph (B), or vendor of personal health records of such individual that is managed, shared, and controlled by or primarily for the individual.".
- (2) Conforming amendment.—Section 13400(11) of the HITECH Act (42 U.S.C. 17921(11)) is amended to read as follows:
- "(11) Personal Health Record.—The term 'personal health record' has the meaning given such term in section 3000(16) of the Public Health Service Act.".

| 1  | (b) Access to Individually Identifiable                |
|----|--|
| 2  | HEALTH INFORMATION.—Section 3001(b) of the Public      |
| 3  | Health Service Act (42 U.S.C. 300jj-11(b)) is amended— |
| 4  | (1) in the matter preceding paragraph (1), by          |
| 5  | inserting "electronic" before "exchange";              |
| 6  | (2) in paragraph (6)—                                  |
| 7  | (A) by inserting "individuals," after "phy-            |
| 8  | sician offices,"; and                                  |
| 9  | (B) by inserting "electronic" before "ex-              |
| 10 | change of health care information";                    |
| 11 | (3) in paragraph (10), by striking at the end          |
| 12 | "and";   |
| 13 | (4) in paragraph (11), by striking the period          |
| 14 | and inserting "; and"; and                             |
| 15 | (5) by adding at the end the following new             |
| 16 | paragraph:   |
| 17 | "(12) allows for an individual to have access to       |
| 18 | their individually identifiable health information.".  |
| 19 | (c) Strategic Plan Relating to Personal                |
| 20 | Health Records.—Section 3001(c)(3)(A) of the Public    |
| 21 | Health Service Act (42 U.S.C. $300jj-11(c)(3)(A)$ ) is |
| 22 | amended by adding at the end the following new clause: |
| 23 | "(ix) The interoperability of a per-                   |
| 24 | sonal health record with an electronic                 |
| 25 | health record.".                                       |

1 (d) Guidelines Relating to Personal Health Records.—Section 3001(c) of the Public Health Service 3 Act (42 U.S.C. 300jj-11(c)) is amended by adding at the end the following new paragraph: 4 5 "(9) Guidelines for Personal 6 RECORDS.—Not later than the date that is 12 7 months after the date of the enactment of the Per-8 sonal Health Record Act of 2009, the National Co-9 ordinator shall develop guidelines for making elec-10 tronic health records interoperable with personal 11 health records for the purpose of improving health 12 care quality, reducing medical errors, and advancing 13 the delivery of patient-centered medical care and 14 health management. Such guidelines shall include— "(A) standards based on the recommenda-15 16 tions provided in section 3002(b)(2)(B)(ix), in-17 cluding for purposes of requiring electronic 18 health records to be made available through 19 electronic exchange and interoperable with per-20 sonal health records for purposes of demonstrating meaningful use of an electronic 21 22 health record under sections 1848(o)(2)(A)(i), 23 1886(n)(3)(A)(i), and 1903(t)(6)(C)(i)(II) of 24 the Social Security Act;

| 1  | "(B) recommendations for applying such a          |
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| 2  | requirement of making electronic health records   |
| 3  | available, with respect to community and behav-   |
| 4  | ioral health programs, in the form of personal    |
| 5  | health records to improve the effective and effi- |
| 6  | cient electronic exchange and management of       |
| 7  | information between the individual (or author-    |
| 8  | ized representative of the individual), including |
| 9  | those in medically underserved communities (as    |
| 10 | defined in section 799B(6)), and community        |
| 11 | health centers and behavioral health service      |
| 12 | providers;  |
| 13 | "(C) required components of a personal            |
| 14 | health record, which shall include—               |
| 15 | "(i) information on medical history               |
| 16 | including diagnoses and procedures, includ-       |
| 17 | ing updates if diagnosis or procedures            |
| 18 | change after each provider encounter;             |
| 19 | "(ii) information on recent laboratory            |
| 20 | results, diagnostic examinations, and             |
| 21 | radiologic procedures, if available in elec-      |
| 22 | tronic format;                                    |
| 23 | "(iii) information on medications and             |
| 24 | prescriptions, both current and historical        |

| 1  | including updates if medications change       |
|----|---|
| 2  | after each provider encounter;                |
| 3  | "(iv) information on allergies, both          |
| 4  | medication and environmental, including       |
| 5  | the specific reaction;                        |
| 6  | "(v) privacy, security, and electronic        |
| 7  | informed consents for disclosing individ-     |
| 8  | ually identifiable health information;        |
| 9  | "(vi) computer programming stand-             |
| 10 | ards determined by the National Coordi-       |
| 11 | nator that allow interoperability of individ- |
| 12 | ually identifiable health information and     |
| 13 | communications between covered entities       |
| 14 | (as defined for purposes of HIPAA privacy     |
| 15 | and security law, as defined in section       |
| 16 | 3009(a)(2)), entities to the extent that      |
| 17 | they engage in activities as business associ- |
| 18 | ates of such covered entities, individuals,   |
| 19 | and vendors of personal health records;       |
| 20 | "(vii) portability of the personal            |
| 21 | health record by the individual between       |
| 22 | covered entities, business associates de-     |
| 23 | scribed in clause (vi), or vendors of per-    |
| 24 | sonal health records;                         |

| 1  | "(viii) ability to use such record as         |
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| 2  | part of the patient intake process;           |
| 3  | "(ix) accurate attribution of the             |
| 4  | source of all data in the personal health     |
| 5  | record, including the source of the infor-    |
| 6  | mation, the date that such information was    |
| 7  | entered into the personal health record,      |
| 8  | and standards-based protection of data        |
| 9  | provided by the health care provider (such    |
| 10 | as health care provider clinic notes, labora- |
| 11 | tory results, diagnostic examinations, and    |
| 12 | radiologic procedures) from changes;          |
| 13 | "(x) notification of the individual in-       |
| 14 | volved or the authorized representative of    |
| 15 | such individual of the risks of withholding   |
| 16 | medical information from a medical pro-       |
| 17 | vider; and                                    |
| 18 | "(xi) health services communication           |
| 19 | tools, including those which offer online se- |
| 20 | cure communication with covered entities      |
| 21 | (as defined for purposes of HIPAA privacy     |
| 22 | and security law, as defined in section       |
| 23 | 3009(a)(2)) and entities to the extent that   |
| 24 | they engage in activities as business associ- |

| 1  | ates (as defined for such purposes) of such     |
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| 2  | a covered entity;                               |
| 3  | "(D) other possible components for consid-      |
| 4  | eration of a personal health record, including— |
| 5  | "(i) an audit trail to monitor who has          |
| 6  | accessed the personal health record of the      |
| 7  | individual;                                     |
| 8  | "(ii) automated appointment, care re-           |
| 9  | minders, and health self-management tools;      |
| 10 | "(iii) the ability to provide education         |
| 11 | tools;  |
| 12 | "(iv) the ability of the individual or          |
| 13 | authorized representative involved to anno-     |
| 14 | tate (without changing) health care pro-        |
| 15 | vider records, such as to provide feedback      |
| 16 | to health care providers of the individual;     |
| 17 | "(v) protection of clinical records in          |
| 18 | the personal health record which are im-        |
| 19 | ported from or exported to a covered enti-      |
| 20 | ty, business associate described in clause      |
| 21 | (i), or vendor of personal health records       |
| 22 | from being changed by the individual, au-       |
| 23 | thorized representative of the individual,      |
| 24 | vendor of personal health records, the cov-     |
| 25 | ered entity, or business associate;             |

| 1  | "(vi) the ability to allow comments by              |
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| 2  | the individual, authorized representative,          |
| 3  | and covered entity within an area of the            |
| 4  | personal health record that is separate             |
| 5  | from the clinical record imported from or           |
| 6  | exported to a covered entity; and                   |
| 7  | "(vii) emergency access procedures for              |
| 8  | medical personnel, with respect to the              |
| 9  | record, for clinical care in cases that the         |
| 10 | individual or authorized representative is          |
| 11 | not able to give consent; and                       |
| 12 | "(E) security, privacy, and electronic in-          |
| 13 | formed consents for disclosing individually iden-   |
| 14 | tifiable health information for personal health     |
| 15 | records, including the recommendations de-          |
| 16 | scribed in paragraph (6)(F).                        |
| 17 | In the case that the Secretary determines that any  |
| 18 | standard or component for personal health records   |
| 19 | included under the guidance under this paragraph is |
| 20 | not adequate pursuant to the report submitted       |
| 21 | under paragraph (6)(F), the Secretary shall notify  |
| 22 | the National Coordinator and the HIT Standards      |
| 23 | Committee in accordance with section 3004(a)(2)(B)  |
| 24 | and the National Coordinator may revise such stand- |
| 25 | ard or component, respectively."                    |

| 1  | (e) Reports.—Section 3001(c)(6) of such Act (42        |
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| 2  | U.S.C. 300jj-11(c)(6)) is amended by adding at the end |
| 3  | the following new subparagraphs:                       |
| 4  | "(F) Monitoring personal health                        |
| 5  | RECORDS.—Not later than the date that is 24            |
| 6  | months after the date of the enactment of the          |
| 7  | Personal Health Record Act of 2009 and annu-           |
| 8  | ally thereafter, the National Coordinator, in          |
| 9  | consultation with the Administrator of the Cen-        |
| 10 | ters for Medicare & Medicaid Services, shall           |
| 11 | submit to the appropriate committees of juris-         |
| 12 | diction of Congress an annual report on—               |
| 13 | "(i) the extent to which personal                      |
| 14 | health records have been integrated into               |
| 15 | the meaningful use of electronic health                |
| 16 | records for purposes of sections                       |
| 17 | 1848(0)(2), $1886(n)(3)$ , and $1903(t)(6)$ of         |
| 18 | the Social Security Act;                               |
| 19 | "(ii) the extent to which the use of                   |
| 20 | personal health records improve commu-                 |
| 21 | nication between individuals and covered               |
| 22 | entities (as defined for purposes of HIPAA             |
| 23 | privacy and security law, as defined in sec-           |
| 24 | tion $3009(a)(2)$ ) and improve patient                |
| 25 | health management, including documenta-                |

| 1  | tion of the extent to which there are cost   |
|----|--|
| 2  | savings;                                     |
| 3  | "(iii) the extent to which the use of        |
| 4  | personal health records, with respect to     |
| 5  | community health centers and behavioral      |
| 6  | health services, improve the effective and   |
| 7  | efficient exchange and management of in-     |
| 8  | formation between the individual involved    |
| 9  | (or authorized representative of the indi-   |
| 10 | vidual), including those in medically under- |
| 11 | served communities, and community health     |
| 12 | centers and behavioral health service pro-   |
| 13 | viders;                                      |
| 14 | "(iv) status of the standards imple-         |
| 15 | mented in paragraph (9)(A) and the need      |
| 16 | to revise or include new standards;          |
| 17 | "(v) the adequacy of the components          |
| 18 | of a personal health record described in     |
| 19 | paragraph (9)(C); and                        |
| 20 | "(vi) the affect of having an individual     |
| 21 | with full access to the medical records of   |
| 22 | such individual through use of a personal    |
| 23 | health record, including—                    |
| 24 | "(I) a prospective study ana-                |
| 25 | lyzing health care utilization (includ-      |

| 1  | ing the impact of personal health            |
|----|--|
| 2  | records on health care provider effi-        |
| 3  | ciency, health care provider reim-           |
| 4  | bursement for time spent interacting         |
| 5  | with individuals as a result of per-         |
| 6  | sonal health records, and defensive          |
| 7  | medicine practices);                         |
| 8  | "(II) the extent that such access            |
| 9  | affects communications by means of           |
| 10 | such records between various health          |
| 11 | care providers of the individual (in-        |
| 12 | cluding the use of provider notations);      |
| 13 | "(III) a prospective study ana-              |
| 14 | lyzing the affect of such access on the      |
| 15 | patient-health care provider relation-       |
| 16 | ship; and                                    |
| 17 | "(IV) the risks and benefits of an           |
| 18 | individual having full access to med-        |
| 19 | ical records of the individual through       |
| 20 | the use of personal health records.          |
| 21 | "(G) RECOMMENDATION RELATING TO SE-          |
| 22 | CURITY AND PRIVACY OF PERSONAL HEALTH        |
| 23 | RECORDS.—Not later than 6 months after the   |
| 24 | date of the enactment of the Personal Health |
| 25 | Record Act of 2009, the National Coordinator |

| 1  | shall submit to the appropriate committees of     |
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| 2  | jurisdiction of Congress a report, including rec- |
| 3  | ommendations, on the technological,               |
| 4  | medicolegal, medical safety, and other pertinent  |
| 5  | issues related to an individual's control of the  |
| 6  | personal health record of such individual and     |
| 7  | shall establish guidelines for such control. The  |
| 8  | National Coordinator shall ensure the participa-  |
| 9  | tion in such a report of health care consumers,   |
| 10 | vendors of personal health records, and covered   |
| 11 | entities (as defined for purposes of HIPAA pri-   |
| 12 | vacy and security law, as defined in section      |
| 13 | 3009(a)(2)), along with other health care stake-  |
| 14 | holders. The report shall encompass at least the  |
| 15 | following issues:                                 |
| 16 | "(i) the rights of an individual uti-             |
| 17 | lizing a personal health record with respect      |
| 18 | to the individual's own individually identifi-    |
| 19 | able health information contained in such;        |
| 20 | and   |
| 21 | "(ii) the security and privacy of an in-          |
| 22 | dividual utilizing a personal health record,      |
| 23 | including—  |
| 24 | "(I) defining who has right of ac-                |
| 25 | cess to an individual's personal health           |

| 1  | record in the case of a personal health   |
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| 2  | record provided by a covered entity;      |
| 3  | "(II) security and privacy issues         |
| 4  | following medical emergency access of     |
| 5  | information in a personal health          |
| 6  | record by health care providers;          |
| 7  | "(III) the impact of an individual        |
| 8  | restricting medical information access    |
| 9  | in a personal health record of such in-   |
| 10 | dividual to health care providers on      |
| 11 | patient care and safety;                  |
| 12 | "(IV) the risks and benefits of           |
| 13 | health care provider notification if the  |
| 14 | personal health record of an individual   |
| 15 | is restricted by the individual;          |
| 16 | "(V) the uses and disclosures of          |
| 17 | the information of an individual con-     |
| 18 | tained in a personal health record that   |
| 19 | should be authorized or required by a     |
| 20 | vendor of personal health records pro-    |
| 21 | viding and maintaining such record;       |
| 22 | "(VI) electronic informed con-            |
| 23 | sents for disclosing individually identi- |
| 24 | fiable health information;                |

| 1  | "(VII) the use of an audit trail of              |
|----|--|
| 2  | who has entered, removed, and                    |
| 3  | changed data within a personal health            |
| 4  | record; and                                      |
| 5  | "(VIII) the dissemination of ab-                 |
| 6  | normal laboratory results, diagnostic            |
| 7  | examinations, and radiological proce-            |
| 8  | dures into personal health records               |
| 9  | prior to notification of the abnor-              |
| 10 | mality by the health care provider.".            |
| 11 | (f) Personal Health Record Standards In-         |
| 12 | CLUDED IN HIT POLICY COMMITTEE RECOMMENDA-       |
| 13 | TIONS.—  |
| 14 | (1) In General.—Section 3002(b)(2)(B) of         |
| 15 | the Public Health Service Act (42 U.S.C. 300jj-  |
| 16 | 12(b)(2)(B)) is amended by adding at the end the |
| 17 | following new clause:                            |
| 18 | "(ix) Standards and implementation               |
| 19 | specifications for the interoperability of       |
| 20 | personal health records and electronic           |
| 21 | health records.".                                |
| 22 | (2) Conforming changes relating to hit           |
| 23 | STANDARDS COMMITTEE RECOMMENDATIONS.—            |
| 24 | (A) DEADLINE FOR SUBMISSION OF REC-              |
| 25 | OMMENDATIONS TO NATIONAL COORDINATOR.—           |

Section 3003(b)(1)(A) of such Act (42 U.S.C. 300jj-13(b)(1)(A)) is amended by adding at the end the following: "Not later than the date that is 6 months after the date of the enactment of the Personal Health Record Act of 2009, the HIT Standards Committee shall recommend to the National Coordinator standards and implementation specifications described in section 3002(b)(2)(B)(ix). The HIT Standards Committee shall update such recommendations and make new recommendations as appropriate, including in response to notification sent under section 3004(a)(2)(B).".

- (B) FORUM.—Section 3003(b)(2) of such Act (42 U.S.C. 300jj-13(b)(2)) is amended by inserting before the period the following: ", including for the adoption of interoperability of personal health records and electronic health records".
- (3) Conforming Changes relating to Adoption of initial set of standards.—Section 3004(b)(1) of such Act (42 U.S.C. 300jj–14(b)(1)) is amended by inserting "(other than clause (ix))" after "section 3002(b)(2)(B)".

- 1 (g) Application of Guidelines to Meaningful
- 2 Use Requirements of Electronic Medical Records
- 3 Under Medicare.—
- 4 (1) Eligible Professional Payment incen-5 TIVES.—Section 1848(o)(2)(A)(i) of the Social Secu-6 rity Act (42 U.S.C. 1395w-4(o)(2)(A)(i)) is amend-7 ed by inserting before the period at the end the fol-8 lowing: "and shall include demonstrating the avail-9 ability of such technology to and use of such tech-10 nology by individuals furnished items and services by 11 such professional in the form of electronic and personal health records consistent with guidelines estab-12 13 lished by the National Coordinator under section 14 3001(c)(9)(A) of the Public Health Service Act".
  - (2) ELIGIBLE HOSPITAL PAYMENT INCENTIVES.—Section 1886(n)(3)(A)(i) of such Act (42 U.S.C. 1395ww(n)(3)(A)(i)) is amended by inserting before the period at the end the following: ", which shall include demonstrating the availability of such technology to and use of such technology by individuals furnished items and services by such hospital in the form of electronic and personal health records consistent with guidelines established by the National Coordinator under section 3001(c)(9)(A) of the Public Health Service Act".

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- 1 (h) Application of Guidelines to Meaningful
- 2 EHR USE REQUIREMENTS UNDER MEDICAID.—Section
- 3 1903(t)(6)(C)(i)(II) of the Social Security Act (42 U.S.C.
- 4 1396b(t)(6)(C)(i)(II) is amended—
- 5 (1) by striking "and" before "that may be
- 6 based"; and
- 7 (2) by inserting before the period at the end the
- 8 following: ", and which shall include demonstrating
- 9 the availability of such technology to and use of such
- technology by individuals furnished items and serv-
- ices by such Medicaid provider in the form of elec-
- tronic and personal health records consistent with
- guidelines established by the National Coordinator
- under section 3001(c)(9)(A) of the Public Health
- 15 Service Act".
- 16 (i) Relationship to Other Laws.—Section 13421
- 17 of the HITECH Act (42 U.S.C. 17951) is amended by
- 18 adding at the end the following new subsection:
- 19 "(c) Health Information Portability and Ac-
- 20 COUNTABILITY ACT, HEALTH CARE PROVIDERS, AND
- 21 Personal Health Records.—Nothing in this subtitle
- 22 or the provisions of or amendments made by the Personal
- 23 Health Record Act of 2009 shall affect the ability of a
- 24 health care provider involved in the direct care of an indi-
- 25 vidual to obtain pertinent information on the medical his-

- 1 tory of such individual from another health care provider
- 2 involved in the medical care of the individual, in accord-
- 3 ance with HIPAA privacy and security law (as defined in
- 4 section 3009(a)(2) of the Public Health Service Act) as
- 5 in effect before the date of the enactment of the Personal
- 6 Health Record Act of 2009.".

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